
POLICY DETERMINATION



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: June 17, 2024**
(See policy history boxes for previous effective dates)

Title: Pneumococcal conjugate vaccine, 21 valent (PCV21), for intramuscular use

Brief Description of Service:

Pneumococcal conjugate vaccine, 21 valent (PCV21), for intramuscular use (Trade Name: CAPVAXIVE)

CAPVAXIVE is designed to provide significantly broader disease coverage against the leading serotypes associated with pneumococcal disease in adults compared with currently licensed pneumococcal vaccines, based, in part, on global serotype epidemiology data in older adults in regions with high pediatric vaccination uptake. CAPVAXIVE specifically targets residual disease in adults with the inclusion of key serotypes common to licensed vaccines and 8 unique serotypes not contained in any currently licensed vaccine. *S. pneumoniae* is also a common cause of bacterial co-infection with influenza A. Bacterial co-infection commonly occurs within the first 6 days of influenza infection and is associated with an increased risk of death. Complex viral, bacterial, and host factors contribute to the pathogenesis of co-infection. Individuals at high risk of developing influenza-related complications including co-infection include adults ≥ 65 years of age and children

Manufacturer: Merck Sharp & Dohme LLC

The U.S. Food and Drug Administration approved this vaccine on 6/17/24.

ACIP voted and approved the vaccine on 6/27/24

Morbidity and Mortality Weekly Report (MMWR) published on 9/12/24

Recommendation:

The pneumococcal conjugate vaccine, 21 valent (PCV21) is established.

It was approved by the U.S. Food and Drug Administration (FDA) on 6/17/24 and was recommended by the Advisory Committee on Immunization Practices on 6/27/24.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

90684

Other codes (investigational, not medically necessary, etc.):

NA

References:

1. Vaccines Licensed for the Use in the United States Vaccines Licensed for Use in the United States | FDA Accessed 9/3/24
2. FDA Capvaxive June 17, 2024 Summary Basis for Regulatory Action - CAPVAXIVE (fda.gov) Accessed 9/3/24
3. Advisory Committee on Immunization Practices (ACIP) Pneumococcal Vaccine Recommendations | Pneumococcal | CDC Readout of Advisory Committee on Immunization Practices Meeting Held June 26 – 28, 2024 | CDC Online Newsroom | CDC Accessed 9/11/24
4. Morbidity and Mortality Weekly Report (MMWR) 9/12/24 Use of 21-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024 | MMWR (cdc.gov) Accessed 9/12/24

Joint Blue Cross/BCN Medical Policy History

Policy Effective Date	Blue Cross Signature Date	BCN Signature Date	Comments
6/17/24	10/17/24		Policy determination – EST (jf) Retro effective to FDA approval date 6/17/24. ACIP voted and recommended the vaccine on 6/27/24. It was published in the Morbidity and Mortality Weekly Report (MMWR) on 9/12/24 Policy determination form is recommended for retirement.

Next Review Date: Policy retired; no longer subject to annual review.